DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms.Paula Torrianni
Cardiovascular Group
Baxter Healthcare Corporation
17221 Red Hill Avenue (Irvine)
P.O. Box 11150
Santa Ana, California 92711-1150

MAY 9 2000

Ref: 00P-0498/CP 1

Dear Ms. Torrianni:

This is in response to your Citizen Petition dated January 20, 2000, and your follow-up letters/amendments dated March 9, 2000, March 27, 2000 and March 30, 2000, in which you requested an exemption/variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, Part 898 of Title 21 of the Code of Federal Regulations. Your request covers devices identified as the Swan-Ganz Bipolar Pacing Catheters 97120F5 and 97130F5 and Chandler Transluminal V-Pacing probe 98100H and 98100.

Your petition dated January 20, 2000 states that these devices should be exempted from the performance standard for three reasons. First, your device is compatible with the external pulse generators marketed by Medtronic, the market leader for external pulse generators. Medtronic received an exemption for certain temporary pacing leads and does not plan to modify their external pulse generator or cable to accept compliant leads. Your petition claims that marketing the Swan-Ganz Pacing catheters and probes that are compliant with the performance standard will create a greater risk than not meeting the performance standard, because the leads will not be compatible with the Medtronic external pulse generator. Second, the Swan-Ganz Pacing catheters and probes contain caps that connect to the end of the electrodes which would reduce the risk of plugging them into an electrical outlet. Third, your device has been marketed for nineteen (19) years without an incident of electrical injury.

I am denying your request for an exemption because your pacing catheter and probes can and should be designed to comply with the performance standard, and cables are available which allow connection to Medtronic pulse generators. Regarding your second argument, I do not believe that the use of caps will fully prevent the possibility of an electrical hazard. Finally, the fact that there have not been any reports of electrical injury for the past nineteen (19) years does not preclude an electrical injury in the future.

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Your amendments dated March 27, 2000 and March 30, 2000 request a 180-day variance from the performance standard for the same devices. This request is being made to allow Baxter time to meet the requirements for the performance standard and to allow customers time to acquire appropriate adapters. If these devices are not available for use by physicians, Baxter believes that there may be some patient risk.

While I am denying your request for a 6 month variance, I am granting a 4 month variance from the performance standard for the manufacture, distribution, and use of the devices identified as the Swan-Ganz Bipolar Pacing Catheters 97120F5 and 97130F5 and Chandler Transluminal V-Pacing probe 98100H and 98100. Such activity should be discontinued once devices that meet the performance standard are available or by September 9, 2000, whichever occurs first. This variance is being granted to avoid the possibility of product shortage. We understand that Baxter holds the majority of the market share (>50%) for these types of devices. Given the critical care setting in which these catheters are used and lack of sufficient numbers of alternative compliant devices, restricting the availability of the Swan-Ganz pacing catheters to the clinical community could pose a serious risk to the public health.

I trust that this is responsive to your request. If additional information is required, please contact Kent Berthold in our Office of Compliance at (301) 594-4648.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations
and Policy
Center for Devices and
Radiological Health

Comment:ESCrumpler:3-7-00
Draft:KABerthold:3-8-00
Comment:ESCrumpler:3-8-00
Telephone Conversation:Klepinski (Medtronic):3-17-00
Re-typed:KABerthold:3-21-00
ODE Review Memorandum:LGabriel:4-28-00
Re-typed:KABerthold:5-1-00
Revised:ESCrumpler:5-3-00
Re-Typed:KABerthold:5-5-00
Reviewed:CEUldriks:5-5-00
Reviewed: Jsheehan:5-5-00